No.F.3-2/2005-Reg-I/(Vol-II)
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
**Drug Regulatory Authority of Pakistan**
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Islamabad, the 10th September, 2021

# CIRCULAR

SUBJECT: - **INSPECTION OF MANUFACTURERS ABROAD FOR REGISTRATION OF FINISHED DRUGS**

I am directed to refer to the subject cited above. All imported finished drug products are registered/renewed subject to inspection of manufacturer abroad.

2. Policy Board of the Drug Regulatory Authority of Pakistan (DRAP) in its various meetings have already exempted inspection of manufacturer abroad in certain scenarios. The Board in its 36th meeting held on 18th March 2021 again deliberated the matter and keeping in view the suggestions/guidelines of WHO for reliance on other regulatory authorities, approved to further expand the scope of exemptions of foreign inspections. Therefore, the consolidated "Policy for inspections of manufacturers abroad" is as under:

a. **Dosage form specific inspection of manufacturer abroad shall be carried out before grant and renewal of registration.**

b. **Products fulfilling below mentioned criteria shall be exempted from dosage form specific inspection of manufacturer abroad:**
   - **Any product approved by regulatory authorities of USA, EU-EMA, Japan, Australia, Canada, Switzerland, UK, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain.**
   - **Any product having approval of minimum three regulatory authorities of former Eastern Europe.**
   - **Any product's manufacturer having GMP certificate (for applied dosage form facility) available on EUDRA-GMDP website. (http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do)**
   - **Any WHO-PQ product and manufacturing facility (section) of such product.**
   - **Any product approved by PIC/S Participating Authority and manufacturing facility (section) of such product. (https://picscheme.org/en/members)**

**c. In case of suspension or cancellation of registration of the product by exporting country or delisting of WHO-PQ status or suspension/cancellation by PIC/S Participating Authority, the registration holders shall be bound to inform the Registration Board about such suspension or cancellation with in fifteen days. In case of non-compliance, the Registration Board may take action as per law against the importer, which may also lead to suspension/cancellation of registration of such product.**

3. It is hereby circulated for compliance and information of all stakeholders.

**(ABDULLAH)** 10/09/21
Additional Director (PE&R)

**Distribution: -**
i. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
iv. Director, MIS Division, with the request to upload on DRAP website.

**Copy for information to: -**
1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
2. Director, Biological Evaluation & Research, DRAP, Islamabad.
3. PS to Chief Executive Officer, DRAP Islamabad.
4. Office File.